THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

WOMEN'S HEALTH CENTER OF WEST VIRGINIA, *on behalf of itself, its staff, and its patients*; and DR. JOHN DOE, *on behalf of himself and his patients*, *Plaintiffs*, v. ASHISH P. SHETH, *in his official capacity as President of the West Virginia Board of Medicine*; and MATTHEW CHRISTIANSEN, *in his official capacity as Secretary of the West Virginia Board of Medicine*, *Defendants*.	Civil Action No. 2:23-cv-00079 Hon.

DECLARATION OF MARK D. NICHOLS, M.D., IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

I, MARK D. NICHOLS, M.D., declare the following:

1. I am a board-certified obstetrician-gynecologist ("OB/GYN") licensed to practice medicine in the State of Oregon. For more than three decades, I have provided the full range of gynecological and obstetric care to women, including contraception-related care, prenatal care, obstetrics, and abortion care, in both hospital and outpatient settings.

2. I received my medical degree from the University of California, Davis in 1979, and completed my residency in the Department of Obstetrics and Gynecology at Oregon Health Sciences University ("OHSU") in 1983. I have been certified by the American Board of Obstetrics and Gynecology since 1985 and have been a Fellow of the American College of Obstetrics and Gynecology ("ACOG") since 1986.

3. I joined the faculty of OHSU when I finished my OB/GYN residency in 1983. I served as the Chief of the Division of General Gynecology and Obstetrics in the Department of

Obstetrics and Gynecology at OHSU in Portland, Oregon between 1988 and 2013. I recently retired from my roles as Professor of Obstetrics and Gynecology at OHSU and the Director of OHSU's Family Planning Fellowship in July 2022. I currently provide reproductive health care, including first and second trimester abortion care, at a number of outpatient clinics on a contract and volunteer basis.

4. I previously served as the Assistant Director of OHSU's OB/GYN Residency Training Program. I have trained over 200 Obstetrics and Gynecology residents and fellows in hospital-based and outpatient-based settings over the course of my career, including in the provision of abortion care in both settings.

5. I currently serve on Planned Parenthood Federation of America's ("PPFA") National Board of Directors. In addition to my academic and administrative roles at OHSU, I served as the Medical Director and Co-Medical Director of Planned Parenthood Columbia Willamette ("PPCW") affiliate from 1994 to 2013. I was also a member of PPFA's National Medical Committee from 1996 to 2002. PPFA's National Medical Committee develops medical standards and guidelines for more than 500 health centers run by Planned Parenthood affiliates around the country.

6. On numerous occasions since 2010, I have provided medical, consulting, and teaching services abroad through Médecins Sans Frontières (Doctors Without Borders) and other organizations in Ethiopia, Ghana, Laos, Nigeria, South Sudan, Tanzania, Vietnam, Malawi, and Zambia. Prior to my full retirement in 2022, I semi-retired by reducing my time at OHSU in 2013, which allows more time to focus on my international work. I continue to provide abortion care and train OHSU fellows and residents to provide abortion care.

7. I have provided obstetric care to thousands of patients, including prenatal care,

labor and delivery, and post-partum care. In addition, I have provided abortions to thousands of women in both the first and second trimester. In many cases, I have provided abortion and obstetrics care to the same woman at different points in her life.

8. I have authored and co-authored dozens of peer-reviewed research articles and chapters in medical textbooks on a variety of women's health topics, including contraception, menstruation, cancers, pregnancy, delivery, and abortion. My research focuses on family planning, with a particular interest in medication and procedural abortion (defined below), emergency contraception, and hormonal contraception. I am or have been a journal reviewer for the *American Journal of Obstetrics and Gynecology*, *Obstetrics and Gynecology*, *Journal of American Medical Women's Association*, *British Journal of Obstetrics and Gynaecology*, *New England Journal of Medicine*, and the *International Journal of Gynecology & Obstetrics*; and I served on the Editorial Board of the journal *Contraception* from 2014 through 2018.

9. I am a member of numerous professional societies and committees, including the Association of Reproductive Health Professionals, ACOG, and the National Abortion Federation, and serve in several appointed or elected positions within those groups. I am a founding member of the Society of Family Planning ("SFP"), an academic society devoted to promoting high-quality, evidence-based research in the area of reproductive health and family planning, and I served as President of the SFP Board of Directors from 2009 to 2011.

10. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction to provide this Court with additional information about how abortion care is extremely safe and thus the additional restrictions placed on legal abortion in West Virginia are not medically necessary; indeed, I cannot conceive of any justification for these requirements. A copy of my curriculum vitae setting forth my experience, education, and credentials in greater detail is attached

as Exhibit A.

I. Abortion Is Common, Safe, and Essential Health Care

11. Abortion is a basic component of comprehensive health care. The most recent data show that approximately 1 in 4 women in the United States will obtain an abortion by the age of 45.[1]

12. Abortion is extremely safe, with a very low risk of complications.[2] A recent, robust analysis of the full spectrum of abortion care in the United States performed by the National Academies of Sciences, Engineering, and Medicine ("NASEM"), a body composed of esteemed experts that was first established by Congress in 1863 to provide independent, objective expert analysis and advice to the nation to inform public policy, concluded that abortion continues to be one of the safest medical procedures or treatments provided in the nation.[3]

13. The mortality risk for abortion is lower than that of many other common procedures. For example, the NASEM analysis also found that in the United States the mortality

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[1] *See* Rachel K. Jones & Jenna Jerman, *Population Group Abortion Rates and Lifetime Incidence of Abortion: United States, 2008–2014*, 107 Am. J. Pub. Health 1904, 1908 (2017).

[2] *See* Ushma D. Upadhyay et al., *Abortion-Related Emergency Department Visits in the United States: An Analysis of a National Emergency Department Sample*, BMC Med., June 14, 2018, at 1, 1 (among women aged 15–49, abortion-related emergency room visits comprise 0.01 percent of all emergency room visits; given the "low rate of major incidents, perceptions that abortion is unsafe are not based on evidence"); Elizabeth G. Raymond et al., *Mortality of Induced Abortion, Other Outpatient Surgical Procedures and Common Activities in the United States*, 90 Contraception 476 (2014) (abortion is as safe or safer than many other commonly performed outpatient procedures).

[3] Nat'l Acads. of Sci., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States* 74–75, 77 (2018) [hereinafter NASEM Report] ("[t]he clinical evidence makes clear that legal abortions in the United States—whether by medication, aspiration, D&E, or induction—are safe and effective."); *see also* Elizabeth G. Raymond et al., *Mortality of Induced Abortion, Other Outpatient Surgical Procedures and Common Activities in the United States*, 90 Contraception 476 (2014) (abortion is as safe or safer than many other commonly performed outpatient procedures).

rate for colonoscopy is 2.9 per 100,000 procedures, the mortality rate for tonsillectomy ranges from 2.9 to 6.3 per 100,000 procedures, and the mortality rate for plastic surgery is 0.8 to 1.7 per 100,000.[4] By contrast, the risk of death associated with legal induced abortion is only 0.6 to 0.7 per 100,000.[5]

14. Serious complications (defined as complications requiring hospitalization, surgery, or blood transfusion) arising from abortion are exceedingly rare; "in the vast majority of studies, they occur in fewer than 1 percent of abortions."[6]

A. Overview of Abortion Methods

15. There are two basic methods of abortion provided in an outpatient setting: procedural and medication.

16. Procedural abortion in the first trimester and early second trimester typically involves the use of gentle suction to empty the uterus (aspiration abortion). Clinicians use a plastic tube, called a cannula, attached to a syringe or electrical pump inserted through a natural orifice (the vagina and cervix) to empty the uterus. This employs the same procedure and instruments used to treat an early miscarriage after embryonic or fetal demise has occurred naturally, and for pregnancies of the same gestational age there is no difference in the risk of complications between a procedure to manage early miscarriage and aspiration abortion.

17. Although aspiration abortions are sometimes referred to as "surgical" abortion, that is a misnomer, as they do not involve what we typically think of as surgery, *i.e.*, an incision into bodily structures. ACOG, the leading professional membership organization for obstetrician-

[4] NASEM Report at 75.

[5] *See id.*

[6] NASEM Report at 77.

gynecologists, develops clinical guidelines, policies, and position statements for the practice of obstetrics and/or gynecology based on committee review of high-quality, peer-reviewed studies and research. In accordance with ACOG's definition of procedures, aspiration abortions are more accurately referred to as abortion procedures.[7] A procedure is a "short interventional technique . . . generally associated with lower risk of complications."[8]

18. Aspiration abortion is routinely, and almost always, provided in an office or clinic setting.[9]

19. The second method of abortion in the first trimester is medication abortion. In the first trimester, the most common medication abortion regimen involves a combination of two prescription drugs, mifepristone and misoprostol, which the patient may take at a location of their choosing, usually at home. Medication abortion is not a "procedure."

20. Mifepristone, commonly known as RU-486 or by the brand name Mifeprex, blocks the body's receptors for progesterone, a hormone necessary to sustain pregnancy.

21. A patient first takes the mifepristone and then takes the second medication, misoprostol (also known by the brand name Cytotec), usually 24- to 48-hours later. The misoprostol causes the uterus to contract and expel its contents, generally within hours. The FDA permits patients to self-administer each drug in a location of their choosing, without clinical supervision. Abortion patients typically take the medications at home or in another location of

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[7] Am. Col. of Obstetricians & Gynecologists, *Position Statement: Definition of "Procedures" Related to Obstetrics and Gynecology* (Jan. 2018), https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/definition-of-procedures-related-to-obstetrics-and-gynecology ("[a] procedure is a short interventional technique that includes the following general categories… non-incisional diagnostic or therapeutic intervention through a natural body cavity or orifice.").

[8] *Id.*

[9] *See infra* ¶¶ 25, 34–35.

their choosing. An identical regimen is offered to patients experiencing miscarriage. The medication regimen is an alternative to management with an aspiration procedure. Miscarriage patients also typically take the medications at home. Unless otherwise specified, when I refer to medication abortion, I am referring to the mifepristone-misoprostol regimen.

22. For some patients, medication abortion offers important advantages over procedural abortion. In my experience, many people who choose a medication abortion have a strong preference for this method. This is also documented in research studies.[10] Many people prefer medication abortion because they go through the experience in the privacy of their homes and at a time of their choosing. Others prefer medication abortion because it feels more "natural" to them to have their body expel the pregnancy rather than have instruments inserted into the uterus by a provider to empty it.

23. Some patients choose medication abortion because of fear or discomfort around a procedure involving instruments. For example, victims of rape and people who have experienced sexual abuse or molestation or other trauma may choose medication abortion to feel more in control of the experience and to avoid further trauma from having instruments placed in their vagina.

II. A Hospitalization Requirement for Procedural Abortion Care is Patently Illogical

24. I understand that West Virginia House Bill 302 ("HB 302") requires that all procedural abortion care be performed within a hospital. In my opinion, this requirement is not only medically unnecessary but patently illogical. Procedural abortion, particularly in the first and early second trimester, is routinely and safely provided in an outpatient setting for the vast majority

[10] *See, e.g.*, Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 Obstetrics & Gynecology 296, 300-01 (2011).

of patients. All clinic- or office-based care, not just abortion, should be provided in a different setting when a patient's individual circumstances dictate that need.

25. As discussed above, abortion is one of the safest medical procedures in the United States, and procedural abortion is almost always performed in an outpatient clinic or office. This has been the case for decades. Recent data show that only 3% of abortions are performed in hospitals, and over 70% of hospitals perform fewer than 30 abortions per year, often under limited circumstances.[11]

26. Complications arising from abortion are very rare, and the vast majority of complications related to abortion are safely and routinely handled in an outpatient setting without the need for hospital treatment. Data demonstrate that only about 0.16% of patients experienced a serious complication (defined as hospital admission, surgery, or blood transfusion) following an aspiration abortion.[12]

27. Of these rare complications, the most common are heavy bleeding, cervical injury or uterine perforation, and infection.

28. Bleeding complications, which are quite rare, are typically treated by interventions that are routinely and safely provided in-office. Depending on the source or severity of the patient's bleeding, a provider might perform a second aspiration procedure (in the case of additional tissue being retained in the uterus), provide medication that causes blood vessels to contract, or apply pressure to the uterus. If these interventions do not work, there are additional, advanced interventions that might need to be performed in a hospital, but these are rarely

[11] Rachel K. Jones et al., *Abortion incidence and service availability in the United States, 2020*, 54 Perspect. Sex Reprod. Health 128, 134 (2022).

[12] NASEM Report at 60 (citing Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175 (2015)).

necessary.

29. For early procedural abortion, cervical injury is rare and can usually be managed in a clinic setting. This may be a tear in the surface of the cervix. Bleeding from that site is usually controlled with direct pressure, or application of medications. These injuries heal on their own. Occasionally, a suture may be needed. All of these interventions can be and are routinely provided in a clinic or office setting without requiring hospital care. Uterine perforation is also rare and may be managed in a clinic or office setting in the majority of cases.

30. In the rare event that a patient experiences infection as a result of aspiration abortion, the infection would typically not develop until days after the procedure. At that time, a patient diagnosed with infection would receive treatment with oral antibiotics on an outpatient basis; *i.e.*, they would take the antibiotics at home or a place of their choosing. Oral antibiotics almost always resolve infection without any long-term or permanent injury to the patient. The use of intravenous ("IV") or intramuscular ("IM") antibiotics to treat infection arising from procedural abortion is rare, and both IV and IM antibiotics can be provided in a clinic setting.

31. Aspiration abortion carries fewer risks than other procedures that are almost always performed in an office setting. For example, intrauterine device ("IUD") insertion is performed in offices and clinic settings. While IUD insertion is an extremely safe procedure, the incidence of uterine perforation is about 1 in 1,000.[13] By comparison, the risk of uterine perforation from aspiration abortion is about 1 in 10,000.[14]

32. Aspiration abortion, like many gynecological procedures, is performed in the same manner, with the same risk profile, regardless of whether it is performed in an office or hospital.

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[13] Sam Rowlands et al., *Intrauterine devices and risk of uterine perforation: current perspectives*, 7 Open Access J. Contracept. 19, 19 (2016).

[14] NASEM Report at 62 (citing Upadhyay, *supra* note 12).

Another example of such a procedure is a loop electrosurgical excision procedure ("LEEP"). During LEEP, a provider uses a wire loop with an electric current to remove a portion of the cervix as part of the diagnosis and treatment of abnormal and/or cancerous cells on the cervix. LEEP can be provided in either setting, but a hospital-based setting is almost never necessary. The procedure is clinically identical when performed in a clinic or hospital setting, and there is no difference in the risk of complications, including bleeding, when the procedure is performed in a hospital.

33. I have provided first and second trimester abortion care in office settings, in outpatient clinics on hospital campuses, and in hospital settings in those rare circumstances when it is medically necessary for a specific patient. Although first trimester and early second trimester aspiration abortion can be performed in either an outpatient clinic/office or hospital-based setting, in my opinion and based on my decades of experience, there simply is no meaningful difference in the procedure or its safety if the procedure is performed in a hospital as opposed to an outpatient clinic, unless there is a legitimate indication for hospital-based care for an individual patient. This is true for other routine gynecological procedures, such as those described above. Moreover, it is typically costlier to perform the procedure in a hospital operating room, because of fees charged by hospitals. Providing abortion care in a hospital setting for all patients will increase the cost of the procedure without any medical benefit. It is simply excessive and unreasonable—and, frankly, a waste of hospital resources—to require a procedure to be performed in a hospital when there is no medical indication or benefit.

34. Indeed, ACOG's guidelines for the provision of abortion care not only do not require that abortions be performed in hospitals, but they find no basis for requiring that abortions be performed in ambulatory surgical centers ("ASC").[15] ASCs are facilities that are required to

[15] Am. Col. of Obstetricians & Gynecologists, Committee Opinion 815, *Increasing Access*

meet certain standards to provide surgeries that may be more complicated and carry greater risk than procedures that are typically performed in an outpatient setting, but for which an overnight stay still is not required. ACOG has strongly condemned laws and regulations that impose more stringent requirements on abortion than on procedures with similar risks as lacking any sound scientific or medical basis.[16]

35. This has also been true for the duration of my career. I have been providing abortion care for over four decades. When I commenced my medical residency in 1979, it was recognized that the vast majority of abortions did not need to be performed in a hospital, and almost all of the abortion care I provided and observed was in an outpatient setting. Even then, requiring all abortions to be performed in hospitals would have been virtually unheard of and considered medically unjustified.

36. Abortion providers determine how to safely provide care based on a patient's specific circumstances. For example, a hospital setting is appropriate for abortion care for a patient who has a rare, but serious, blood clotting disorder that places the patient at risk of heavy bleeding. In these circumstances, the patient's heavy bleeding risk is so significant that the provider should have access to a blood bank. As another example, a hospital setting is also appropriate for patients with certain types of advanced cardiac disease and/or limited lung function who need certain types of monitoring and care by an anesthesiologist that is only available in an operating room.

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to Abortion, 136 Obstetrics & Gynecology 107, 109 (2020).

[16] *See id.*; Brief for Am. Col. Of Obstetricians & Gynecologists et al. as Amici Curiae Supporting Plaintiffs-Appellees, *Planned Parenthood of Greater Texas v. Abbott*, 2013 WL 6837500, at *4 (2013) (No. 13-51008).

37. However, it makes no sense to require *all* patients to have such a routine, common outpatient procedure in a hospital just because there may be some patients whose unique circumstances prevent them from obtaining outpatient care.

38. As is the case with any outpatient provider, clinics and offices providing procedural abortion should and do have established protocols that dictate how to ensure patient hospital transfer in the rare event that it is necessary. These protocols establish the roles that each member of the patient's care team plays in safely transferring the patient and assign tasks such as getting additional help in the procedure room, calling an ambulance, and notifying the patient's emergency contact. These processes ensure that abortion clinics are well prepared to safely and efficiently transfer patients in the rare cases that is indicated.

39. Of course, just as there are some patients who should not be seen in an outpatient setting, there are some procedures that should be provided in a hospital. For example, among Ob/Gyn patients, those who require cesarean sections, laparoscopies and hysterectomies will require hospital care. The hospital setting is chosen because of the risk of complications associated with those procedures, the severity of those potential complications and the possibility of long-term injury. The resources and personnel to manage those issues are present in a hospital but not in an office or clinic setting.

40. Medical ethics, medical licensure standards, and practice guidelines from professional societies (*e.g.*, ACOG) all provide additional support and safeguards for a physician's determination of the appropriate setting in which to provide medical care. Individual institutions, *e.g.*, a clinic's or office's practices and protocols, also establish their own protocols and practices to assure the safe delivery of medical care. It makes no sense for a legislature to disrupt physicians' ability to make this determination when there is no reason such an intervention is necessary.

41. It is simply illogical to impose a categorical restraint on the setting in which abortion can be provided, when it has been exceedingly safely and routinely performed in outpatient clinic settings for decades.

III. Requiring Medication Abortion Prescribers to Maintain Hospital Privileges is Irrational and Would Do Nothing to Enhance the Excellent Safety Profile of Medication Abortion

42. I am extremely familiar with medication abortion safety because I was one of the principal investigators of the mifepristone clinical trials that led to its approval by the FDA in 2000. I was also involved in research that led to improvements to the medication abortion regimen, which are now reflected in the manufacturer's updated, FDA-approved label. As the medical director for PPCW, I oversaw the first medication abortion program in any Planned Parenthood affiliate in the country. I have personally provided medication abortion care to several hundred patients, and have supervised and consulted for medication abortion care for several thousand patients.

43. I understand that HB 302 requires physicians who prescribe medication abortion drugs to maintain privileges at a West Virginia hospital. In my expert opinion, this requirement is also patently illogical. Medication abortion is extremely safe, with an extremely low risk of complications, and any of the extremely rare complications would emerge hours or days after the patient starts the drug regimen and could be managed by an emergency physician. I cannot conceive of any way in which the requirement that an abortion provider maintain hospital privileges would enhance the safety of the medication abortion process.

44. To date, more than four million women have had a medication abortion in the United States. Major complications from medication abortion are extremely rare, and far rarer

than those associated with continuing a pregnancy and childbirth.[17] Scientific literature and FDA study and action repeatedly affirm the safety of medication abortion and the low risk of complications. For example, the FDA's recent approval of a revised mifepristone label reflects that clinical data continue to confirm that medication abortion is extremely safe.[18] More recently, after reviewing drug safety data, the FDA allowed for the expansion of mifepristone distribution not just through a patient's health care provider, but also through retail pharmacies, where misoprostol has been available for decades.[19] And a recent report from the FDA confirms that the risk of death associated with medication abortion is lower than that associated with use of penicillin or Viagra,[20] none of which, it is my understanding, require hospital privileges to prescribe in West Virginia, nor have I ever heard of that being a requirement in any other state. FDA data show that even Tylenol, which is sometimes prescribed in large doses or in combination with other

[17] *See, e.g.*, NASEM Report, *supra* note 3, at 55–56.

[18] U.S. Food & Drug Admin., *Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation* (Jan. 24, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[19] *See id.*

[20] U.S. Food & Drug Admin., *Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2021,* https://www.fda.gov/media/154941/download (last visited Jan. 26, 2023); *see also* Advancing New Standards in Reprod. Health, *Analysis of Medication Abortion Risk and the FDA report "Mifepristone US Post-Marketing Adverse Events Summary through 6/30/2021*," The Regents of the University of California (Nov. 18, 2022), https://www.ansirh.org/research/brief/analysis-medication-abortion-risk-and-fda-report-mifepristone-us-post-marketing ("[a]n updated review of the data shows that medication abortion continues to be very safe. In fact, it is safer than continuing a pregnancy to term or using other common medications administered in outpatient settings, such as penicillin, Viagra, or Tylenol."); *see also* David A. Grimes, *Risks of mifepristone abortion in context*, 71 Contraception 161 (2005) (risk of death from medication abortion is "virtually identical" to risk of death from miscarriage).

prescription medications, is more lethal than medication abortion, and yet there is no requirement Tylenol prescribers maintain hospital privileges.[21]

45. According to the FDA, serious adverse events (including death, hospitalization, serious infection, and bleeding requiring transfusion) among mifepristone patients are "exceedingly rare, generally far below 0.1% for any individual adverse event."[22] In the extremely rare case that they arise, complications can be safely and effectively managed by any physician trained in providing emergency care, regardless of whether that physician prescribed the patient the medication abortion regimen. This is because medication abortion induces the physiological equivalent of a miscarriage, and emergency care doctors routinely manage complications related to miscarriage.

46. It is highly unlikely that a medication abortion patient will experience a complication that requires hospital care. Less severe complications, while still extremely rare, can be safely handled in an office or clinic setting. For example, if the patient exhibits symptoms of retained pregnancy tissue, that can be managed at an office or clinic with additional medication or a follow-up procedure to remove the tissue. And minor infection can typically be treated with oral antibiotics, which can be prescribed by an abortion provider and ingested by the patient at home.

47. Patient education about how to monitor and seek help for any signs of complications such as heavy bleeding is routine and standard. While each provider has their own specific protocols surrounding patient education, all providers inform the patient of when and where to seek help if any questions or complications arise. Given the millions of medication

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[21] *See id.*

[22] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., *Application Number 020687Orig1s020: Medical Reviews,* 1, 38 (Mar. 2016) https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf.

abortion patients who have safely received medication abortion care, these patient education processes are effective.

48. While the exact definition and scope of hospital privileges varies from hospital to hospital, in my experience hospital privileges designate a provider's hospital staff membership, their responsibilities and obligations as a member of hospital staff, and the scope of the care they are permitted to provide at that specific hospital.

49. Generally speaking, the types of providers with hospital privileges are those who have a hospital-based specialty, such as a surgery, or those who practice in a specialty in which hospital admission is common, such as cardiology. Given the nature of such a provider's practice, a provider with privileges might have responsibilities such as treating patients at the hospital, providing emergency care coverage for the hospital, and voting on hospital governance issues.

50. Whether a provider has privileges simply does not affect the safety of non-hospital care that they provide or demonstrate anything about the provider's qualifications to provide that care; it is universal in medicine for a provider to help a patient transition to another provider if that patient eventually needs more specialized care or care in a different setting than that physician can provide. And whether a provider has privileges has no bearing on whether, for example, their patient receives necessary care at a hospital in the event that hospital care is necessary; the patient can receive emergency care from emergency department staff, an on-call physician, or specialty care from another provider. And for patients who already have to travel long distances to obtain care, whether their provider has hospital privileges has no bearing on whether that patient receives necessary care at a hospital after the patient has returned home, because the patient is unlikely to go to a hospital where that provider has privileges anyway. I cannot conceive of any reason why obtaining privileges with a hospital would affect a provider's ability to safely provide medication

abortion to patients or improve outcomes for patients.

51. Many physicians do not have hospital-based practices, and therefore do not maintain privileges with hospitals. Indeed, it is common for a hospital to require that a provider admit a minimum number of patients to the hospital annually in order to maintain privileges. This helps ensure that hospitals extend their resources to staff members who will actually treat patients at the hospital, and is an economic consideration and not a reflection of an individual provider's skill or experience. Providers who provide the majority of their patient care in an office or clinic setting may not be able to meet this minimum admission requirement, depending on their specialty. This is true for many abortion providers who do not provide other forms of hospital care; both procedural and medication abortion are so safe that these providers simply would not be able to admit enough patients for hospital care to be eligible for privileges.

52. Based on my decades of experience practicing medicine, I cannot conceive of any reason why hospital privileges would be necessary for the prescription of a medication.

53. After evaluating peer-reviewed evidence and clinical guidelines addressing safe outpatient care, ACOG concluded that "[m]andates that abortion providers obtain hospital admitting privileges are one example of government restrictions that are not based in science, improperly regulate medical practice, and impede patients' access to quality, evidence-based care." This is because, in part, privileges requirements are not necessary to support continuity of care between outpatient settings and hospitals, and because "[g]aining admitting privileges is not tied to patient care and is unrelated to a clinician's competence." ACOG further found that privileges are not only medically unnecessary but, in light of the divide between hospital-based and outpatient care in modern medicine, are potentially "impossible" for abortion providers to obtain. In particular, because of the fact that "[a]bortion is one of the safest medical procedures

performed in the United States," ACOG noted that it is "extremely rare" that abortion will result in complications allowing a provider to meet the minimum quota of hospital patients often required by privilege applications.[23]

54. The requirement that a medication abortion provider have hospital privileges also conflicts with FDA and NASEM findings, both of which are grounded in exhaustive reviews of medication abortion safety data.

55. For example, while the FDA requires health care providers to meet certain qualifications in order to order and dispense Mifeprex, having hospital privileges is not one of those requirements.[24]

56. NASEM reports that "[n]o special equipment or emergency arrangements are required for medication abortions" and there is "no evidence indicating that clinicians that perform abortions require hospital privileges to ensure a safe outcome for the patient." Instead, requiring hospital privileges is the type of policy that "diminish[es] . . . quality care," including by reducing access to abortion.[25]

57. NASEM further determined that "[t]here is no evidence that the dispensing or taking of [medication abortion pills] requires the physical presence of a clinician."[26] In other words, a physician does not need to be present when the patient takes the medication.

58. Indeed, there is no risk of complications arising shortly after a patient takes

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[23] Am. Col. of Obstetricians & Gynecologists, *Hospital Admitting Privilege Mandates Undermine Physician Practice and Unduly Burden Women's Access to Abortion*, https://www.acog.org/news/news-articles/2020/11/hospital-admitting-privilege-mandates-undermine-physician-practice-and-unduly-burden-womens-access-to-abortion (last visited Jan. 29, 2023).

[24] *See supra* note 18.

[25] NASEM Report at 14, 11-12.

[26] *Id.* at 79.

mifepristone that would warrant a requirement that a prescriber maintain hospital privileges. While there is a risk of a quickly developing allergic reaction with any medication, an allergic reaction to mifepristone is extremely unlikely; I have provided or supervised the provision of medication abortion to thousands of patients, none of whom have had an allergic reaction to mifepristone. To my knowledge, there are no documented reports of any patient ever having an allergic reaction to mifepristone.

59. Although any serious complications from medication abortion are extremely rare, one of the rare complications would likely occur hours or days after the patient ingests misoprostol, which occurs 24-48 hours after the patient takes mifepristone. This is because, as discussed above, misoprostol causes the uterus to contract and expel its contents, giving rise to the rare risk of bleeding and infection. These complications can be safely managed by any physician trained in emergency care, and do not necessarily require treatment from the prescribing physician.

60. In my opinion, it is entirely irrational to require hospital privileges for physicians providing medication abortion when complications from medication abortion are so rare, would only arise days or hours after the patient has left the provider's office, and do not require treatment from the prescribing physician. There is no connection between a prescriber having privileges and whether the patient can get the hospital-based care they need in the extremely unlikely event that the need arises.

IV. These Requirements are Deeply Harmful to the People of West Virginia

61. Abortion is significantly safer than carrying a pregnancy to term.[27] The risk of death following childbirth is approximately 14 times greater than that associated with abortion.[28] Childbirth also carries higher risks of complications: for example, the amount of bleeding that occurs with aspiration abortion is significantly less than with childbirth, and consequently the likelihood of bleeding requiring blood transfusion is much less.

62. Moreover, nearly three percent of all women who give birth vaginally have a prolonged hospital admission or early re-admission to the hospital. For cesarean delivery (also known as a C-section; a major operation that more than 30 percent of American women have when they give birth), the figure is more than three times higher.[29] Even though C-sections are relatively common, C-sections are major abdominal surgeries that carry risks of hemorrhage, infection, and injury to internal organs. Vaginal deliveries can also cause hemorrhage and infection, and can lead to injury, such as pelvic floor damage, organ and muscle prolapse, vaginal tearing and scarring, and incontinence.

63. Even an uncomplicated pregnancy poses challenges to a person's entire physiology and stresses most major organs including the heart and lungs, which must work harder during pregnancy.

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[27] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 216-17 (2012) [hereinafter Raymond & Grimes, *Comparative Safety*].

[28] *Id.* at 217.

[29] Patricia R. Hebert et al., *Serious Maternal Morbidity After Childbirth: Prolonged Hospital Stays and Readmissions*, 94 Obstetrics & Gynecology 942, 944 (1999); Brady E. Hamilton et al., *Births: Preliminary Data for 2011*, Nat'l Vital Stat. Rep. Oct. 3, 2012, at 1, 5.

64. Access to abortion care is extraordinarily important, and when medically unnecessary and unjustified restrictions, such as the hospitalization and privileges requirements discussed above, reduce or eliminate this access, the effects are extremely harmful. Abortion is safe, necessary health care, and forcing pregnant people to carry their pregnancies to term against their will threatens their physical and mental health. HB 302 prevents physicians from providing essential, safe, and compassionate health care with no medical basis.

65. Lack of access to safe abortion also has profound effects on a person's health and safety as well as families' financial wellbeing. The Turnaway Study, a recently published prospective study, analyzed (i) people seeking abortion who were unable to obtain abortion care and were forced to carry their pregnancy to term and (ii) those who were able to obtain an abortion, and compared outcomes in the five years after either obtaining or being denied abortion care. Prospective cohort studies use continuous or repeated measures to follow a particular group or "cohort" of individuals over a prolonged period of time in order to examine the relationship between certain variables and outcomes. This type of study design is very helpful for examining trends and changes over time and produces the highest quality evidence. This is because this study design overcomes many of the common weaknesses in studies examining the impact of abortion of women, including recall bias, failure to control for confounding variables, and limited information on outcomes. The results of the Turnaway Study demonstrate the harmful effects of being denied a wanted abortion.

66. For example, the Study found that patients who were unable to obtain wanted abortions experienced worse physical health outcomes and increased risk of physical violence from the partner involved in the pregnancy when compared with patients who received desired

abortion care.[30] The Study also found that being denied an abortion resulted in large and persistent negative effects on financial well-being, including lower rates of employment and higher rates of poverty observed in the four years after being denied an abortion.[31]

67. Further, the Study found that children born as a result of a denied abortion are more likely to live in households with lower incomes relative to the FPL and more likely to live in households with less financial resources to pay for basic living expenses, relative to the future children of people who obtained a wanted abortion.[32]

68. I have provided abortion care to many patients who are pregnant as a result of rape or incest. The experience of pregnancy is traumatic for almost all of these patients, and their pregnancy is an emotionally distressing reminder of their experience of assault. These patients have expressed profound relief when they have been able to access abortion care. Having to deny abortion care to rape or incest survivors stops providers from being able to provide compassionate, safe health care. And requiring a rape or incest survivor to continue their pregnancy against their will is extraordinarily cruel. If a victim of rape or incest is unable to access wanted abortion care,

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[30] Advancing New Standards in Reprod. Health, *Turnaway Study*, The Regents of the University of California, https://www.ansirh.org/research/turnaway-study (last visited Jan. 31, 2023) [hereinafter the "Turnaway Study"]; Sarah C.M. Roberts et al., *Risk of Violence from the Man Involved in the Pregnancy After Receiving or Being Denied an Abortion*, BMC Med., Sept. 29, 2014, at 1, 5; Lauren J. Ralph et al., *Self-Reported Physical Health of Women Who Did and Did Not Terminate Pregnancy After Seeking Abortion Services: A Cohort Study*, 171 Annals of Internal Med. 238, 240 (2019); Sarah Miller et al., *The Economic Consequences of Being Denied an Abortion*, Nat'l Bureau of Econ. Rsch., Working Paper No. 26662, at 11 (2022), http://www.nber.org/papers/w26662.

[31] The Turnaway Study; Miller et al., *supra* note 30, at 7, 27.

[32] The Turnaway Study; Miller et al., *supra* note 30, at 27; Diana Greene Foster et al., *Comparison of Health, Development, Maternal Bonding, and Poverty Among Children Born After Denial of Abortion vs After Pregnancies Subsequent to an Abortion*, 172 JAMA Pediatrics 1053, 1053 (2018).

they will be forced to experience emotionally distressing reminders of their trauma each day while they are pregnant, in medical offices when they are seeking prenatal care, and at delivery.

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69. In sum, in my opinion and experience, the additional restrictions placed on legal procedural and medication abortion in West Virginia are medically unjustified, and entirely illogical. To the extent these requirements prevent abortion providers from otherwise providing safe, compassionate health care, these requirements undermine the safety and well-being of pregnant people.

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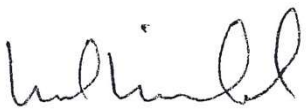
I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: February 1, 2023



MARK D. NICHOLS, M.D.